MIRADA medical

510(k) Summary of Safety and Effectiveness

JUN 23 2010

Date of summary:	23 March 2010
Submitter's name:	Mirada Medical Ltd
Submitter's address:	Innovation House, Mill Street, Oxford, OX2 0JX, United Kingdom
Submitter's contact:	Gwilym Owen
Telephone number:	+44 (0)1865 811172

Device Proprietary Name:	Mirada XD
Device Common Name(s):	XD4/ XD3 (NM)/XD3 NM Edition/XD3
Classification Name:	Class II: Picture Archiving and Communications System (892.2050) Product Code: LLZ

Mirada XD is Substantially Equivalent to the following Legally Marketed devices:

Predicate Devices

510(k) Number	Trade Name	Manufacturer
K071964	MiM 4.1 (SEASTAR)	MIMvista Corp.
K091373	Syngo TrueD Software	Siemens Medical Solutions USA, Inc
K093982	XELERIS 3 PROCESSING AND REVIEW WORKSTATION	GE Healthcare
KO33955	RTist	Mirada Solutions Ltd

1.1.1 Intended Use

Mirada XD is intended to be used by trained medical professionals including, but not limited to, radiologists, nuclear medicine physicians, and physicists.

Mirada XD is a software application intended to display and visualize 2D & 3D multi-modal medical image data. The user may process, render, review, store, print and distribute DICOM 3.0 compliant datasets within the system and/or across computer networks. Supported modalities include, CT, MR, PET, SPECT and planar NM. The user may also create, display, print, store and distribute reports resulting from interpretation of the datasets.

Mirada XD allows the user to register combinations of anatomical and functional images and display them with fused and non-fused displays to facilitate the comparison of image data by the user. The result of the registration operation can assist the user in assessing changes in

image data, either within or between examinations and aims to help the user obtain a better understanding of the combined information that would otherwise have to be visually compared disjointedly.

Mirada XD provides a number of tools such as rulers and region of interests, which are intended to be used for the assessment of regions of an image to support a clinical workflow. Examples of such workflows include, but are not limited to, the evaluation of the presence or absence of lesions, determination of treatment response and follow-up.

Mirada XD allows the user to define, transform and store and export regions of interest structures in DICOM format including RT format for use in radiation therapy planning systems.

1.1.2 Device Description

Mirada XD is a software application for displaying and visualizing 2D & 3D multi-modal medical image data such as CT, MR, PET, SPECT and planar NM. Mirada XD runs on a workstation with color monitor(s), keyboard, mouse and optional CD-RW. Mirada XD is designed to enable rendering, reviewing, storing, printing and distribution of DICOM 3.0 compliant datasets and reports within the system and/or across computer networks.

Mirada XD enables automatic and manual registration of combinations of anatomical and functional images that can be displayed with fused and non-fused displays to facilitate the comparison of image data by the user.

Mirada XD provides a number of tools such as rulers and region of interests through SUV calculation for the assessment of regions of an image to support a clinical workflow. Mirada XD also allows users to define, transform, store and export regions of interest structures in DICOM format including RTSS format for use in radiation therapy planning systems.

1.1.3 Testing

Mirada XD is validated and verified against its user needs and intended use by the successful execution of planned performance, functional and algorithmic testing included in this submission. The results of performance, functional and algorithmic testing demonstrate that Mirada XD meets the user needs and requirements of the device, which are demonstrated to be substantially equivalent to those of the listed predicate devices.

Verification and Validation for Mirada XD has been carried out in compliance with the requirements of ISO 13485:2003 and in adherence to the DICOM standard.

In conclusion, performance testing demonstrates that Mirada XD is substantially equivalent to, and performs at least as safely and effectively as the listed predicate devices. Mirada XD meets requirements for safety and effectiveness and does not introduce any new potential safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mirada Medical, Ltd.
Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUN 23 2010

Re: K101228
Trade/Device Name: Mirada XD
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 3, 2010
Received: June 4, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K101228

Device Name: Mirada XD

Indications for Use:

Mirada XD is intended to be used by trained medical professionals including, but not limited to, radiologists, nuclear medicine physicians, and physicists.

Mirada XD is a software application intended to display and visualize 2D & 3D multi-modal medical image data. The user may process, render, review, store, print and distribute DICOM 3.0 compliant datasets within the system and/or across computer networks. Supported modalities include, CT, MR, PET, SPECT and planar NM. The user may also create, display, print, store and distribute reports resulting from interpretation of the datasets.

Mirada XD allows the user to register combinations of anatomical and functional images and display them with fused and non-fused displays to facilitate the comparison of image data by the user. The result of the registration operation can assist the user in assessing changes in image data, either within or between examinations and aims to help the user obtain a better understanding of the combined information that would otherwise have to be visually compared disjointedly.

Mirada XD provides a number of tools such as rulers and region of interests, which are intended to be used for the assessment of regions of an image to support a clinical workflow. Examples of such workflows include, but are not limited to, the evaluation of the presence or absence of lesions, determination of treatment response and follow-up.

Mirada XD allows the user to define, transform and store and export regions of interest structures in DICOM format including RT format for use in radiation therapy planning systems.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101228